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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,930	10/11/2001	Michael Poirier	560.09-US1	4572

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/977,930

Applicant(s)

POIRIER ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by

Pourahmadi et al., 6,440,725.

Pourahmadi discloses a container having at least one flexible wall (column 22, line 13), a fluid receiving port (column 4, line 2), a fluid discharge port (column 4, line 2), and a plurality of compartments (141, 143) fluidly coupled to at least one of the fluid receiving port and the fluid discharge port; wherein the fluid port receives a continuous flow of a biological fluid that includes a target antigen (column 2, lines 58-65; column 6, lines 46-50; column 9, lines 52-54; column 18, lines 40-45), and wherein the fluid discharge port emits a continuous flow of the biological fluid that is at least partially depleted from the target antigen (column 6, lines 46-50; column 6, lines 46-50; column 9, lines 52-54; column 18, lines 40-45); wherein at least one of the compartments further comprises a plurality of magnetic beads (column 18, line 43) that carry an affinity

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marker that binds the target antigen; and wherein the target antigen is separated from the biological fluid using a magnetic force and an automatic mechanical force (column 18, lines 42-50; and column 22, lines 11-14), wherein at least one of the magnetic force and automatic mechanical force is transmitted through the flexible wall (column 22, lines 11-14).

As to claim 2, at least one of the compartments includes a buffer fluid (column 10, line 2).

As to claim 3, the affinity marker is an antibody (column 12, line 27; column 17, line 39).

As to claim 4, at least one of the compartments further includes a port that allows draining of the at least one of the compartments (column 4, line 2).

As to claim 5, the biological fluid comprises whole blood (column 5, line 54).

As to claim 6, the target antigen is present on a bacterium (column 2, line 5).

### ***Response to Arguments***

Applicant's arguments filed June 29, 2004 have been fully considered but they are not persuasive. Applicant argues that Pourahmadi's beads are not used to carry any affinity marker, but are merely used as an aid to mixing.

In response, Examiner reasserts that Pourahmadi's beads carry an affinity marker, since Pourahmadi specifically discloses that the "beads can be functionalized with various binding agents" (col. 18, lines 44-45.)

Other disclosures in Pourahmadi supports Examiner's position that the beads carry an affinity marker. Pourahmadi states that suitable solid supports for capturing an analyte include beads (see for example, column 2, lines 62-64; column 3, lines 46-47; column 6, lines 27-28; column 17, lines 22-23; column 30, lines 63-64; column 31, lines 11-12; and column 33, lines 44-46.)

In short, the Pourahmadi magnetic beads can be used to mix fluids (col. 18, lines 49-50), and they can also carry binding agents (col. 18, lines 44-45.) That is, these two capabilities are not exclusive. It is understood that these binding agents are used for capturing analyte since Pourahmadi discloses that beads are solid supports for capturing an analyte (see for example, col. 2, lines 62-64.)

As to the obviousness-type double patenting rejection, that rejection is hereby withdrawn in view of the filed terminal disclaimer which has been approved.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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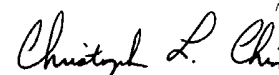
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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PRIMARY EXAMINER  
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9/14/07